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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/333,966

Applicant(s)

Yu et al.

Examiner

John Ulm

Group Art Unit

1646



☒ Responsive to communication(s) filed on Aug 18, 2000

☒ This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 27-46 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 27-46 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

1) Claims 27 to 46 are pending in the instant application. Claim 43 has been amended as requested by Applicant in Paper Number 9, filed 18 August of 2000.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 27 to 46 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for those reasons of record in section 2 of Paper Number 5.

Applicant has traversed this rejection on the premise that it is in conflict with the "REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS". Applicant is encouraged to review example 12 of the guidelines which expressly addresses the subject of orphan receptors such as the protein of the instant invention.

Applicant's reliance on *In re Brana*, 51 F.3d 1560,1566, 34 USPQ2d 1436 ,1441 (Fed. Cir. 1995) is misplaced. That court decision determined that a compound which belonged to a family of compounds known to have anti-tumor activity, which is a common and well established specific and substantial utility for that family of compounds, would be reasonably expected to have anti-tumor activity in light of positive *in vitro* data with respect to that particular compound since that data has proven to be an indicator of anti-cancer activity by other members of that family. The protein of the instant invention does not belong to a family of compounds with a

Art Unit: 1646

common well established specific and substantial utility. The utility of those members of the receptor family to which the claimed protein in the instant application belongs lies in the knowledge that they modulate a specific physiological activity in response to a specific ligand. Since the instant specification does not disclose the identity of a native ligand for the claimed protein, a knowledge of the pathway through which that receptor transduces its signal in response to that ligand is not particularly useful.

Applicant urges that the claimed protein has utility because its overexpression in a cell leads to cell death. Applicant has failed to explain the practical benefit of this property. Virtually any compound in sufficient concentration, including sodium chloride, water, and sucrose, will cause the death of a cell. This is the very principle upon which food preservation has been based for centuries. It is also old and well known in the art of molecular biology that almost any protein, when expressed in a sufficiently high level in a cell, will kill that cell. This is why so much developmental work was done in the 1970's and 1980's to develop expression vectors with regulatable and inducible promoters. Therefore, the fact that a protein of the instant invention can cause cell death when overexpressed in a cell does not provide a specific and substantial utility since there appears to be no selectivity for this action which is disclosed in the instant specification as advantageous for a particular and practical purpose.

5) Claims 27 to 46 also stand rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a credible, substantial and

Art Unit: 1646

specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6) Applicant's arguments filed 18 August of 2000 have been fully considered but they are not persuasive for those reasons given above.

7) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

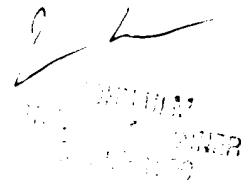
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature is written over a circular official stamp. The stamp contains the text "UNITED STATES PATENT AND TRADEMARK OFFICE" around the perimeter and "SUPERVISOR" in the center.